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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,272	08/04/2006	Mauro Ajani	622-96	7152

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EXAMINER	
WHEELER, THURMAN MICHAEL	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
10/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,272	AJANI ET AL.	
	Examiner	Art Unit	
	Thurman Wheeler	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-33,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-33, 45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/05/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 23-33, 45 and 46 are pending in instant application

1. The information disclosure statement (IDS) dated 05 August 2010 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits.

2. Rejections not reiterated in this Office Action are withdrawn.

3. Herein, claims 23-33, 45 and 46 are for further prosecution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a

background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
2. Ascertaining differences between the prior art and claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 23-33, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelm et al (US 20030203004, of Record) in view of Villa et al (EP 1183014, IDS).

Applicants' claimed invention is directed towards an oral pharmaceutical or dietary composition containing at least one short-chain fatty acid or salt, ester and/or amide thereof, in combination with a complex sugar and/or dietary fibre. Oral pharmaceutical or dietary composition comprising, as active ingredients, at least one short-chain fatty acid or salt, ester and/or amide thereof, in combination with a complex sugar and/or dietary fibre in which the complex sugar and/or dietary fibre is selected from inulin, pectin, dextrin, maltodextrin or derivatives thereof and with one or more pharmacologically acceptable excipients, said composition comprising (a) matrix consisting of the lipophilic compounds with a melting point lower than 90 °C and optionally amphiphilc compounds in which the

active ingredient are at least partially incorporated (b) an amphilphilic matrix; and (c) an outer hydrphilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed.

Kelm teaches an oral or dietary pharmaceutical composition comprising short and long chain fatty acids, wherein short chain fatty acid components are selected from the group consisting of acetic acid, propionic acid, butyric acid, esters thereof, salts thereof, and mixtures thereof [0012-0016]. Further, Kelm teaches that the ester chain of the selected acid may be a straight or branched chain of carbon atoms which is hydrolyzable in the presence of mammalian digestive enzymes, and typically contains from 1 to about 5 carbon atoms [0041].

Kelm teaches dosage forms may comprise from about 0.0001% to about 50% of the short chain fatty acid, by weight of the composition [0043]. Kelm teaches tablet or capsule forms comprise from about 1% to about 50% of the short chain fatty by weight of the composition [0044].

Kelm teaches compositions comprising short chain fatty acids mixed with fiber. Kelm teaches fibers that include complex carbohydrates, e.g. pectins [0091-0092]. Further, Kelm teaches a composite dietary fiber (e.g., citrus albedo fiber containing cellulose and pectin) [0094].

Kelm teaches a composition comprising fiber in a quantity from 0.001% to about 15%, preferably from about 0.01% to about 10%, more preferably from about 0.1% to about 10% [0095].

Kelm teaches the compositions comprise an enteric delivery system, preferably a small intestinal enteric delivery system, e.g. for delivery of the short chain fatty acids to the small intestine, the short chain fatty acids may be combined with a component having a pH of about 5.5 or greater, such that the short chain fatty acids bypass the stomach unabsorbed and are delivered specifically to areas of the small intestine. This may be particularly advantageous wherein the short chain fatty acid is the free acid, e.g. not an ester of acetic, propionic, or butyric acid. Further, Kelm teaches enteric delivery systems are commonly known [0105].

Kelm teaches the compositions can comprise additional optional components to, for example, enhance their performance or to otherwise render the composition more suitable for use as an industrial or consumer product. Non-limiting examples of optional components are given below: water, carbohydrates, sweeteners, coloring and flavoring agents, protein components, nutrients, and fiber ([0060]-[0095]).

However, the Kelm reference does not embody a composition comprising (a) matrix consisting of the lipophilic compounds

with a melting point lower than 90 °C and optionally amphiphilc compounds in which the active ingredient are at least partially incorporated (b) an amphilphilic matrix; and (c) an outer hydrphilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed.

Villa teaches a controlled release and taste masking oral pharmaceutical composition containing an active ingredient, comprising (a) matrix consisting of the lipophilic compounds with a melting point lower than 90 °C and optionally amphiphilc compounds in which the active ingredient are at least partially incorporated (b) an amphilphilic matrix; and (c) an outer hydrphilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed [0018]. Furthermore, Villa teaches that this three component matrix structure can be used for the control of the dissolution of an active ingredient to modulate the dissolution of the active ingredient in aqueous and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract [0001]. Villa teaches the compositions can further contain conventional excipients, i.e. chitosan and acrylic polymers [0034]

It would have been obvious to one skilled in the art at the time of the invention to modify the oral or dietary pharmaceutical composition comprising a small intestinal enteric

delivery system for the delivery of short chain fatty acids to the small intestine as taught by Kelm to provide a controlled release and taste-masking delivery system comprising a three component matrix whereby the active ingredient is released in the gastrointestinal tract as taught by Villa.

Thus, one of ordinary skill in the art would have had a reasonable amount of expectation of success to provide a pharmaceutical composition as claimed by Applicants by following the teachings of Kelm and Villa, as a whole.

Conclusions

5. All claims are rejected.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on 9:00 a.m.-5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635